

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
 (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>AY/PL/j1/2007.3442</b>	<b>FOR FURTHER ACTION</b>  See Form PCT/IPEA/416	
International application No. <b>PCT/SG2007/000398</b>	International filing date (day/month/year) <b>17 November 2007</b>	Priority date (day/month/year) <b>17 November 2006</b>
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <b>C08F 251/00 (2006.01)      A61F 9/00 (2006.01)      G02C 7/04 (2006.01)</b>		
Applicant <b>AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH et al</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.  2. This REPORT consists of a total of <b>5</b> sheets, including this cover sheet.  3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <b>3</b> sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).	
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I      Basis of the report <input checked="" type="checkbox"/> Box No. II      Priority <input type="checkbox"/> Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV      Lack of unity of invention <input checked="" type="checkbox"/> Box No. V      Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input checked="" type="checkbox"/> Box No. VI      Certain documents cited <input type="checkbox"/> Box No. VII      Certain defects in the international application <input type="checkbox"/> Box No. VIII      Certain observations on the international application	

Date of submission of the demand <b>17 September 2008</b>	Date of completion of this report <b>10 November 2008</b>
Name and mailing address of the IPEA/AU <b>AUSTRALIAN PATENT OFFICE          PO BOX 200, WODEN ACT 2606, AUSTRALIA          E-mail address: pct@ipaaustralia.gov.au          Facsimile No. +61 2 6283 7999</b>	Authorized Officer <b>CATHY DOUGLAS</b> AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61 2 6283 2664

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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## Box No. I Basis of the report

1. With regard to the **language**, this report is based on:
- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages **1, 3-9, 11-30, 34 (abstract)** as originally filed/furnished
- pages\* **2, 10** received by this Authority on **17 September 2008** with the letter of **17 September 2008**
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- ☒ the claims:
- pages **32,33** as originally filed/furnished
- pages\* as amended (together with any statement) under Article 19
- pages\* **31** received by this Authority on **17 September 2008** with the letter of **17 September 2008**
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- ☒ the drawings:
- pages **1/7-7/7** as originally filed/furnished
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- pages\* received by this Authority on \_\_\_\_\_ with the letter of \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_
5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to the Authority under Rule 91 (Rule 70.2(e)).

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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## Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
- The right to the priority claim is found to be valid.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1-25	YES
	Claims NONE	NO
Inventive step (IS)	Claims 1-25	YES
	Claims NONE	NO
Industrial applicability (IA)	Claims 1-25	YES
	Claims NONE	NO

## 2. Citations and explanations (Rule 70.7)

D1 US 2006/0235162; D2 WO 2006/014138; D3 US 2002/0165324; D4 WO 2002/039948;  
D5 US 2005/0271729; D6 US 2005/0148682; D7 JP 06-239942; D8 JP 63-309914; D9 US 2007/0293648;

D10 LEACH, Jennie B. et al, "Characterization of protein release from photocrosslinkable hyaluronic acid-polyethylene glycol hydrogel tissue engineering scaffolds", BIOMATERIALS, 26, (2005), pages 125-135

D11 INSUP, Noh et al, "Effects of cross-linking molecular weights in a hyaluronic acid-poly(ethylene oxide) hydrogel network on its properties", BIOMEDICAL MATERIALS. 1 (2006) 116-123

NOVELTY (N)

None of D1-D8 or D10-D11 disclose a polymeric matrix defining interconnected pores cross-linked with a wetting agent. Nor is method for forming such a polymer as defined in claim 1 disclosed. Thus claims 1-25 are considered to fulfil the requirements of novelty under the PCT.

Note: D9 was published after the International Filing Date of the present application – See Box VI

INVENTIVE STEP (IS)

D2 is considered the closest prior art. D2 discloses a transparent, porous polymer formed from a bicontinuous microemulsion of water, monomer and copolymerizable surfactant. The microemulsion further comprises a drug which is dispersed in the formed polymer or the pores thereof. Paragraph 41 discloses that the drug may be a lubricating agent. Further, paragraph 43 discloses that the "drug is incorporated, either in the polymer or the pores, or both". Incorporation into the polymer refers to dispersion in the polymer matrix as per paragraph 40. The drug is releasable from the polymer when it is in contact with a liquid. Thus, D2 does not suggest a cross-linked drug incorporated into the polymer

D1 discloses that hyaluronic acid can be polymerized into a copolymer via a mono-unsaturated compound. However, D1 does not disclose or suggest that the hyaluronic acid component would be releasable from the polymer on use. Thus, there is no motivation for the person skilled in the art to combine D1 and D2 to obtain the presently claimed invention. Therefore, claims 1-25 are considered to possess an inventive step.

INDUSTRIAL APPLICABILITY

Claims 1-25 are considered industrially applicable, as they relate to processes and products useful in industry.

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## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date ( valid claim) (day/month/year)
US 2007/0293648 A1	20 December 2007	27 April 2007	28 April 2006

US 2007/0293648 discloses a hyaluronic acid-containing biopolymer wherein HA is retained by cross-linking, useful for making contact lenses. However, as there is no disclosure of a polymer matrix having interconnected pores, the document cannot be considered relevant to the present claims.

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day/month/year)Date of written disclosure  
referring to non-written disclosure  
(day/month/year)

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acid. The cross-linkable wetting agent may be an acrylated hyaluronic acid, such as a methacrylated hyaluronic acid. After polymerization, an unbonded portion of the wetting agent may be dispersed in the polymer and the pores, and the unbonded portion of the wetting agent may be releasable from the material. The wetting agent may comprise polyvinylpyrrolidone or dextran. The monomer may be methyl methacrylate or 2-hydroxyethyl methacrylate. The surfactant may be a zwitterionic surfactant, such as 3-((11-acryloyloxyundecyl)-imidazolyl) propyl sulfonate. The microemulsion may comprise from about 0.1 to about 0.5 wt%, such as from about 0.25 to about 0.35 wt%, of the wetting agent. The microemulsion may comprise from about 15 to about 50 wt% of the water, from about 5 to about 40 wt% of the monomer, and from about 10 to about 50 wt% of the surfactant.

[0005] In accordance with another aspect of the present invention, there is provided a porous polymeric material formed according to a method described herein.

[0006] In accordance with further aspect of the present invention, there is provided a porous material comprising a transparent polymer matrix defining interconnected pores; and a wetting agent, at least a portion of the wetting agent cross-linked with the polymer matrix. The wetting agent may comprise methacrylated hyaluronic acid (MeHA), and at least a portion of the MeHA may be cross-linked with the polymer matrix. The wetting agent may comprise an acrylated hyaluronic acid (AHA), and at least a portion of the AHA may be cross-linked with the polymer matrix. The wetting agent may comprise an unbonded portion dispersed in one or both of the polymer matrix and the pores, and the unbonded portion of the wetting agent may be releasable from the material. The wetting agent may comprise a hyaluronic acid, polyvinylpyrrolidone or dextran. The polymer matrix may comprise polymerized methyl methacrylate or 2-hydroxyethyl methacrylate. The material may comprise from about 0.1 to about 0.5 wt%, such as from about 0.25 to about 0.35 wt%, of the wetting agent. The pores may have a pore diameter of about 60 to about 120 nm.

[0007] In accordance with another aspect of the present invention, there is provided a contact lens comprising a porous polymeric material described herein.

molecules may travel faster in the pores than in polymer 12 when the pores are filled with a liquid.

[0046] Conveniently, the release of the wetting agent can be maintained for a long period of time such as more than 20 days in exemplary embodiments of the present invention because WA 14 is dispersed in the pores and polymer 12, with some cross-linked with the polymer matrix. Initially, WA dispersed in the pores is quickly released at a high release rate. The high release rate may last, for example, a few days. The release rate will then decrease as the initially freely dispersed WA molecules in the pores have already been mostly released. The release of the unbonded wetting agent, however, can continue for a relatively long period of time at a lower release rate, as the unbonded WA dispersed in the polymer slowly move into the pores and diffuse from the inner regions of contact lens 10 to the lens surface.

[0047] Conveniently, the cross-linking of a portion of the wetting agent with the polymer matrix may also provide improved strength to the porous material.

[0048] When contact lens 10 is worn by a user, the improved wettability of the lens surface can reduce dry eye symptoms, allergic reactions, and discomfort resulting from dry eye conditions and wearing the contact lens. If the optional unbonded WA is present, it can be continuously released into the eye, which may further improve the performance of the contact lens.

[0049] In one embodiment, polymer 12 may be prepared by polymerizing a bicontinuous microemulsion that contains one or more copolymerizable monomers, one or more surfactants copolymerizable with at least one of the monomers, water and a WA, such that the resulting polymer has interconnected pores filled with an aqueous liquid. The WA is dispersed in the microemulsion before polymerization, such as in the aqueous domains. The microemulsion may also include a polymerization initiator, such as a photo initiator. Conveniently, at least a portion of the WA also serves as a cross-linker. Thus, in some embodiments, no additional cross-linker is required. In other embodiments, an additional cross-linker may be included in the microemulsion.

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## WHAT IS CLAIMED IS:

1. A method of forming a porous polymeric material, comprising:  
  
polymerizing a bicontinuous microemulsion comprising water, a wetting agent, a monomer, and a surfactant copolymerizable with said monomer, to form a polymer defining interconnected pores,  
  
wherein said wetting agent comprises a cross-linkable wetting agent such that after said polymerizing, at least a portion of said cross-linkable wetting agent is cross-linked with said polymer.
2. The method of claim 1, wherein said cross-linkable wetting agent is an acrylated hyaluronic acid.
3. The method of claim 1, wherein said cross-linkable wetting agent is a methacrylated hyaluronic acid.
4. The method of any one of claims 1 to 3, wherein after said polymerizing, an unbonded portion of said wetting agent is dispersed in said polymer and said pores, said unbonded portion of said wetting agent being releasable from said material.
5. The method of any one of claims 1 to 4, wherein said wetting agent comprises a hyaluronic acid.
6. The method of any one of claims 1 to 5, wherein said wetting agent comprises polyvinylpyrrolidone or dextran.
7. The method of any one of claims 1 to 6, wherein said monomer is methyl methacrylate or 2-hydroxyethyl methacrylate.
8. The method of any one of claims 1 to 7, wherein said surfactant is a zwitterionic surfactant.
9. The method of claim 8, wherein said zwitterionic surfactant is 3-((11-acryloyloxyundecyl)-imidazolyl) propyl sulfonate.